UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

COLLEEN JAEGER AND WILLIAM JAEGER, Plaintiff(s), V. HOWMEDICA OSTEONICS CORP., Defendant(s).	NO. C 15-00164 MEJ JOINT CASE MANAGEMENT STATEMENT

Plaintiffs Colleen Jaeger and William Jaeger, and Defendant Howmedica Osteonics Corp ("HOC"), hereby submit the following Rule 26(f) report.

1. Jurisdiction and Service:

Plaintiffs originally filed a Complaint in the Southern District of Illinois along with several other plaintiffs. Defendants filed a motion to sever the various plaintiffs and transfer venue to the appropriate jurisdictions. On January 13, 2015, the Southern District of Illinois severed Plaintiffs Colleen Jaeger and William Jaeger's claims and transferred their action to this Court.

This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332 because the Plaintiff and the Defendants are citizens of different states and the claimed amount in controversy exceeds $75,000.00, exclusive of interest and costs.

2. Facts:

Plaintiffs: Plaintiff Colleen Jaeger participated in a clinical trial of a device called "CerviCore." HOC brought the CerviCore device to a clinical trial, proposing that it would be an alternative to traditional fusion ("ACDF") surgery for patients who had a damaged disc in their cervical spine.

Plaintiffs allege the device itself is faulty and dangerous. Its design causes two metal plates to grind against each other and release metal debris, which can cause metallosis or metal poisoning.

HOC used poor manufacturing methods that worsened the problem.

Plaintiffs also allege HOC conducted the clinical study improperly and outside the allowed scope. HOC hid adverse events, misled its study doctors, and misled study participants. Plaintiffs' allegations are—or will be—supported by medical evidence, experts, and the device designers themselves. HOC purchased the CerviCore device from its inventors and those inventors later sued HOC alleging HOC mishandled the manufacturing of the device and clinical trial so badly it cost the inventor profits. HOC eventually abandoned the device and terminated the clinical study.

When it terminated the study, HOC promised to care for patients who have device-related medical problems. It has refused every request for care, however. After a number of years of worsening health and growing problems with the CerviCore device, Ms. Jaeger's doctor determined the CerviCore device was the cause of the problem and explanted it. In addition to the device, he removed a quantity of silvery fluid from around Ms. Jaeger's spinal cord and sent it all to Howmedica for analysis. The doctor confirmed she was suffering from metallosis. Ms. Jaeger's condition has improved, but she has not fully recovered. She is showing the signs of bone necrosis due to poisoning by the device and may need additional surgeries. Some pain continues.

The Jaegers initially joined other plaintiffs in bringing an action in the Southern District of Illinois. At HOC's request, that Court severed the claims and transferred them to various districts, this matter being one of them. Ms. Jaeger's fellow plaintiffs are all victims of CerviCore with similar facts; some of their experiences may be relevant to his case.

Defendant: HOC denies the allegations in Plaintiff's Statement, above. HOC denies any liability in this case and denies that the subject device was defective in any way. The CerviCore Disc was an investigational device undergoing clinical trial pursuant to an Investigational Device Exemption ("IDE") granted by the FDA. HOC complied with the requirements of the IDE in all respects and worked closely with the FDA throughout the process. Proper informed consent was obtained from all study participants, including Plaintiff Colleen Jaeger.

3. Legal Issues:

Plaintiffs: Plaintiffs dispute Defendant's claim of preemption and have considerable evidence to refute that affirmative defense. Defendants acted outside the scope of any FDA approval, made promises to Ms. Jaeger and her doctors, and breached the agreement it entered into with study participants. Discovery disputes have raised an additional set of legal issues currently being heard in other courts.

Defendant: Ultimately, all of Plaintiffs' claims will be preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360k, to the Federal Food, Drug and Cosmetics Act ("FDCA"). *See Riegel v. Medtronic*, 128 S. Ct. 999 (2008). Investigational devices, like the CerviCore, which have been approved for an IDE, undergo an investigational process that is at least as rigorous as the pre-market approval ("PMA") process, and, thus, the body of preemption law governing PMA devices applies equally to IDE devices. *See, e.g., Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3rd Cir. 1994). HOC reserves the right to move on the pleadings and/or for summary judgment at the appropriate time for dismissal of the Complaint and any Amended Complaint based on preemption. HOC also reserves the right to move based on other defenses, including but not limited to any applicable statutes of limitations.

4. Motions:

Currently, there are no pending motions in this action.

5. Amendment of Pleadings:

The parties request that Plaintiffs be given until May 1, 2015 to file an Amended Complaint, and that Defendant be given until June 5, 2015 to respond.

6. Evidence Preservation:

The parties have taken steps to preserve relevant documents and evidence bearing on the parties' claims and defenses in this matter. Ms. Jaeger underwent revision surgery to remove the

CerviCore device on November 6, 2012. Ms. Jaeger's surgeon returned the explanted device along with biological samples to Howmedica.

7. Disclosures:

Defendant requests the parties serve Initial Disclosures on or before May 5, 2015. Plaintiffs request the parties serve Initial Disclosures prior to the conference on April 21, 2015.

8. Discovery:

The parties have not yet commenced discovery in this action. Proposed discovery deadlines are set forth below.

Defendant requests that the parties be limited to 35 document requests and 20 Requests for Admission.

Plaintiffs object to Defendant's proposed discovery limits and ask the Court retain the limits in the Federal Rules. This litigation is highly complex and involves a wide variety of issues. Defendant has resisted attempts at discovery in other courts and Plaintiffs ask they not be restricted in number so that they can prosecute the case efficiently.

Defendant disagrees with plaintiffs' statement that it has "resisted" discovery in other matters as this implies that plaintiffs' requests have been reasonable and appropriately narrow in scope, which they have not.

9. Class Actions:

Not applicable.

10. Related Cases:

Plaintiffs: Ms. Jaeger's original eight co-plaintiffs' cases are related and are in the courts listed below. Furthermore, additional CerviCore cases are soon to be filed as well as cases involving a sister product, FlexiCore (which was a metal-on-metal lumbar prosthesis, as opposed to this cervical prosthesis, made by the same inventors and defendant).

Carol McGrew	S.D. Ill.
Phyllis Ann Good	E.D. Mich.
Thomas and Terri Lyn Day	D. Colo.

Rebecca Kaspers	W.D. Wash.
Jackie and Steven Parks	M.D. Fla.
Stephen and Tara Pepke	E.D. Mich.
Donna Zaretzka	D. S.C.
Angela and Donald Moneymaker	E.D. Virg.

Defendant: There are no related cases or proceedings. The plaintiffs and the claims originally filed under one Complaint in the Southern District of Illinois have been severed and transferred to their respective jurisdictions.

11. Relief:

Plaintiffs: Plaintiffs' claim is for economic damages, non-economic damages, punitive damages, and other relief as the Court sees appropriate.

Defendant: HOC has not filed a counterclaim seeking any affirmative relief.

12. Settlement and ADR:

The parties previously filed a Stipulation and Proposed Order Selecting ADR Process, wherein the parties agreed to a private mediation with JAMS by March 31, 2016.

13. Consent to Magistrate Judge for All Purposes:

The parties previously filed a declination of consent.

14. Other References:

The parties agree that this case is not suitable for binding arbitration or a special master.

15. Narrowing of Issues:

The parties are not aware of any need to narrow the issues through stipulated facts or bifurcation of claims or defenses.

16. Expedited Trial Procedure:

The parties do not believe this action is appropriate for an expedited schedule or streamlined procedures.

17. Scheduling:

The parties request the following discovery deadlines:

Fact Discovery Completion:	February 12, 2016
Plaintiff's Rule 26(a)(2) Disclosures:	March 4, 2016
Defendants' Rule 26(a)(2) Disclosures:	April 11, 2016
Expert Discovery Completion:	May 20, 2016
Daubert & Dispositive motion filing deadline:	June 15, 2016

18. Trial:

Plaintiffs have demanded a jury trial. The parties estimate a ten (10) to twelve (12) day trial.

19. Disclosure of Non-party Interested Entities or Persons:

The parties are unaware of any interested parties other than the named Plaintiffs and Defendant.

20. Professional Conduct:

The attorneys of record for the parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

21. Other matters:

The parties anticipate the filing of a Stipulated Protective Order prior to exchange of confidential documents and information.

Dated: April 14, 2015

Respectfully submitted,

ANDRUS ANDERSON LLP
155 Montgomery Street, Suite 900
San Francisco, CA 94104
Tel. (415) 986-1400
Fax. (415) 986-1474
Lori@andrusanderson.com

By */s/ Lori E. Andrus*
Lori E. Andrus

ZOLL, KRANZ & BORGESS, LLC
6620 West Central Avenue- Suite 100
Toledo, OH 43617
Tel. (419) 841-9623
Fax. (419) 841-9719
Email: jim@zkblaw.com

By:____/s/*James O'Brien* (PHV)__
James O'Brien

SEDGWICK LLP

By____*/s/ Mario Horwitz*_____
Mario Horwitz
James Nelson
801 S. Figueroa St., 19th Floor
Los Angeles, CA 90017
Tel: (213) 426-6900
Fax: (213) 426-6921
E-mail: Mario.horwitz@sedgwicklaw.com

GIBBONS P.C.

By:_____/s/ *Paul Asfendis*_____
Kim M. Catullo, Esq. (*to apply for admission pro hac vice*)
Paul E. Asfendis, Esq. (*to apply for admission pro hac vice*)
One Pennsylvania Plaza, 37th Floor
New York, New York 10119

Attorneys for Defendant
Howmedica Osteonics Corp

ATTESTATION PURSUANT TO GENERAL ORDER NO. 45

Pursuant to General Order No. 45 of the Northern District of California, I attest that concurrence in the filing of this document has been obtained from the other signatory to this document.

By: */s/ James Nelson*
James Nelson